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EFFECTIVENESS AND SAFETY OF LABETALOL VERSUS NIFEDIPINE FOR HYPERTENSIVE DISORDERS OF PREGNANCY: A COMPARATIVE STUDY OF MATERNAL CARDIOVASCULAR AND NEONATAL OUTCOMES

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ABSTRACT

Background: Hypertensive disorders of pregnancy remain a major cause of maternal and perinatal morbidity. Labetalol and nifedipine are commonly used for blood pressure management; however, comparative evidence regarding their maternal cardiovascular safety and neonatal outcomes remains clinically important.

Objective: To compare the effectiveness and safety of labetalol and nifedipine in women with hypertensive disorders of pregnancy, with particular emphasis on maternal blood pressure control, obstetric complications, and neonatal outcomes.

Methods: This comparative observational study included 188 pregnant women managed at the Departments of Gynaecology and Obstetrics and Cardiology, Liaquat University of Medical and Health Sciences, Hyderabad/Jamshoro, Pakistan, over eight months beginning in August 2025. Participants were equally allocated to the labetalol (n = 94) and nifedipine (n = 94) groups. Maternal outcomes included successful blood pressure control, additional antihypertensive therapy, hypotension, eclampsia, HELLP syndrome, intensive care unit admission, and mode of delivery. Neonatal outcomes included preterm birth, low birth weight, neonatal intensive care unit admission, low five-minute Apgar score, and stillbirth. Data were analysed using IBM SPSS Statistics version 27, with statistical significance defined as $p < 0.05$.

Results: Successful blood pressure control was achieved in 83.0% of women receiving labetalol and 87.2% receiving nifedipine ($p = 0.413$). No statistically significant between-group differences were observed in the assessed maternal complications or neonatal outcomes.

Conclusion: Labetalol and nifedipine demonstrated comparable outcomes in this cohort. Further adequately powered studies using verified clinical data are warranted to establish their comparative effectiveness and safety across different hypertensive disorders of pregnancy.

KEYWORDS: Antihypertensive Agents; Hypertension, Pregnancy-Induced; Labetalol; Maternal Outcomes; Nifedipine; Pregnancy Outcome.

INTRODUCTION

Hypertensive disorders of pregnancy (HDP) remain a major cause of maternal and perinatal morbidity and mortality, contributing to complications ranging from placental dysfunction and fetal growth restriction to eclampsia, stroke, and maternal organ failure. The clinical spectrum includes chronic hypertension, gestational hypertension, pre-eclampsia, and eclampsia, each associated with distinct pathophysiological mechanisms and risks. The consequences extend beyond delivery, as affected women may also experience increased long-term cardiovascular risk. Timely recognition, appropriate blood pressure control, and careful maternal and fetal surveillance are therefore central to the management of these disorders (1, 2).

Management of hypertension during pregnancy must be a balance between mitigating maternal symptoms while preserving adequate uteroplacental perfusion. Severe hypertension (e.g. systolic BP ≥160 mmHg and/or diastolic BP ≥110 mmHg) is a medical emergency since a sustained increase in blood pressure will predispose to cerebrovascular or other life-threatening complications in the mother. In case of non-severe hypertension decisions in treatment depend on the primary disorder, gestation age, severity of blood pressure and maternal clinical status. Current guidelines advocate for antihypertensive therapy, if indicated, but differ in treatment thresholds and targets depending on the clinical context (3, 4).

Background Labetalol and nifedipine are commonly used antihypertensive agents for the treatment of hypertension in pregnancy given their established clinical applicability across treatment settings. Blood pressure is lowered by labetalol through combined α- and β-adrenergic blockade, whereas the calcium-channel blocker nifedipine acts to promote vasodilation via prevention of calcium entry into vascular smooth muscle. Both

agents are utilized in pregnancy; however, their pharmacological profiles, routes of administration, dosing schedules, contraindications and adverse-effect patterns differ. Thus, the choice of treatment should take into account the severity of hypertension, comorbidities in the mother, contraindications to drugs and rapid or long-term control of blood pressure (5).

Comparative evidence between both agents has been mixed. Labetalol and modified-release nifedipine produced broadly similar blood pressure control in women with chronic hypertension but the study was not powered to ascertain differences in infrequent maternal or neonatal outcomes (6). On the other hand, trials examining acute severe hypertension have examined rate of blood pressure fall, treatment failure and number of doses. According to a systematic review and meta-analysis, oral nifedipine reached target blood pressure faster than intravenous labetalol whereas no noted statistical significance in the incidence of multiple maternal/neonatal complications were seen (7). This should not be generalised across acute treatment and maintenance therapy as the clinical indications, drug formulations and outcome measures are different.

The comparative observational evidence base remains sparse, and often contradictory. Differences in fetal growth restriction and fetal heart-rate abnormalities between treatment groups were confined to a number of selected subgroups, and the study was limited by design and confounding (8). A more recent systematic review and network meta-analysis of randomized trials concluded there was no systematic superior or worse efficacy overall for labetalol compared to nifedipine on most maternal and perinatal outcomes, but some analysis found differences that suggested potential superiority of each drug specifically in pre-eclampsia (labetalol) and preterm births (nifedipine). The certainty of comparative conclusions was limited given that the underlying evidence is low-to-moderate quality (9).

While both medications have been used for a long time, there is still uncertainty about the relative effectiveness in terms of improved maternal-fetal outcomes and safety given the unique patient population with differing phenotypes of hypertensive disorders of pregnancy. Variations in patient characteristics, illness severity, gestational age, indication for treatment and common clinical practice may affect maternal and neonatal outcomes. The importance of the local clinical evidence is further emphasized as medication selection and monitoring practices may vary from one healthcare system to another. However, observational comparisons would require them to adjust for confounding by indication because women on one agent are likely different systemically from those receiving the other.

We sought to compare the safety and efficacy of labetalol and nifedipine in women with hypertensive disorders of pregnancy at Liaquat University of Medical & Health Sciences, Hyderabad/Jamshoro, Pakistan. The objective of the study was to characterize the comparative clinical performance between both treatments in the primary (maternal cardiovascular and obstetric outcomes) and secondary charted neonatal outcomes.

METHODOLOGY

This comparative observational study was conducted at the Department of Gynaecology and Obstetrics and the Department of Cardiology, Liaquat University of Medical & Health Sciences, Hyderabad/Jamshoro, Pakistan. The study was conducted over eight months from August 2025 to March 2026. It compared maternal cardiovascular, obstetric, and neonatal outcomes among pregnant women with hypertensive disorders of pregnancy who received labetalol or nifedipine.

Women were eligible for inclusion if they had (1) a documented diagnosis of a hypertensive disorder of pregnancy during the index pregnancy; (2) received labetalol or nifedipine for blood pressure management during that pregnancy; and (3) had clinical records available to determine treatment group and the study outcomes. Women were excluded if the records did not establish the diagnosis or antihypertensive agent received, or if the records lacked the information required to classify the prespecified primary outcome.

A total of 220 pregnant women were assessed for eligibility. Thirty-two were excluded after eligibility assessment, and 188 patients were included in the final study sample: 94 in the labetalol group and 94 in the nifedipine group. The patient enrollment and treatment-group allocation are presented in Figure 1.

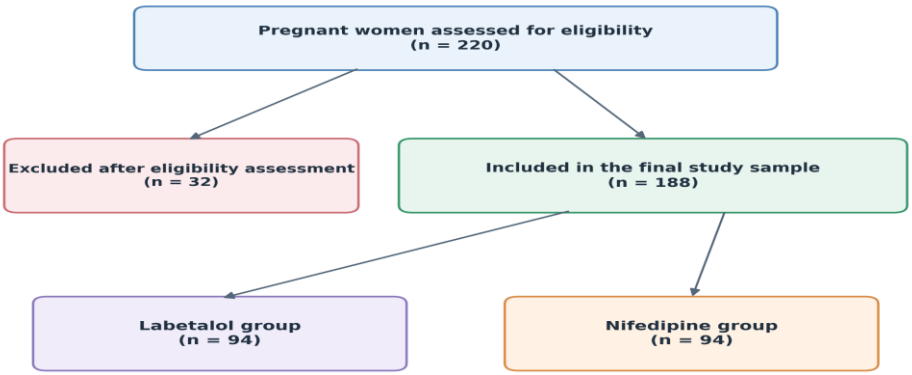

Figure 1. Flow diagram of patient enrollment and treatment-group allocation.

Standardised data-collection form were used to extract baseline and 30-day follow-up or hospitalisation data from clinical records. Maternal demographic and obstetric characteristics, gestational age, hypertensive disorder subtype and severity, recorded blood pressure measurements, antihypertensive treatment details, relevant comorbidities and maternal cardiovascular, obstetric and neonatal outcome data were extracted.

We applied a total-population sampling approach to include all eligible patient records during the eight-month study period. The definitive sample consisted of 188 patients, including 94 treated with labetalol and 94 treated with nifedipine. The sample size was determined by the number of eligible patients as a function of the available record data during a defined period without an a priori power calculation. Thus, no prespecified power level or minimum detectable treatment effect was assumed.

Data were analyzed using IBM SPSS Statistics for Windows version 27.0 (IBM Corp., Armonk, NY, USA). Frequencies and percentages were used to summarize categorical variables. Continuous variables that were approximately normally distributed were summarized as mean and standard deviation, while those that were skewed (>1), were summarized using median and interquartile range (IQR). For comparison between groups, independent-samples t-test or Mann–Whitney U test for continuous variables and chi-square test or Fisher's exact test for categorical variables were used as appropriate. Where possible, effect estimates with 95% confidence intervals were reported. Multivariable analyses were performed where the number of outcome events justified modelling and the necessary confounders were available. All tests were two-sided; $p < 0.05$ was considered statistically significant.

RESULTS

Participant characteristics

A total of 188 patients were included in this analysis, with 94 in the labetalol group and 94 in the nifedipine group. Mean maternal age was 29.8 ± 5.7 years in the labetalol group and 30.2 ± 5.5 years in the nifedipine group. Mean gestational age at presentation was 32.1 ± 4.2 and 31.8 ± 4.4 weeks, respectively. The baseline characteristics did not indicate statistically significant between-group differences **(Table 1)**.

Characteristic	Labetalol (n=94)	Nifedipine (n=94)	p-value
Maternal age, years	29.8 ± 5.7	30.2 ± 5.5	0.625
Gestational age, weeks	32.1 ± 4.2	31.8 ± 4.4	0.633
Systolic BP, mmHg	146.8 ± 12.4	147.5 ± 11.9	0.693
Nulliparous, n (%)	43 (45.7)	46 (48.9)	0.661
Pre-eclampsia, n (%)	56 (59.6)	53 (56.4)	0.658

Continuous data are mean ± standard deviation; categorical data are n (%).

Maternal outcomes

In the comparison, successful blood-pressure control was recorded in 78 patients (83.0%) receiving labetalol and 82 (87.2%) receiving nifedipine ($p = 0.413$). Additional antihypertensive therapy was required in 18 (19.1%) and 13 (13.8%) patients, respectively ($p = 0.326$). Maternal hypotension occurred in 7 (7.4%) and 10 (10.6%) patients ($p = 0.446$). Eclampsia, HELLP syndrome, and ICU admission were uncommon in both simulated groups. Caesarean delivery occurred in 51 (54.3%) patients in the labetalol group and 48 (51.1%) in the nifedipine group **(Table 2)**.

Outcome	Labetalol (n=94)	Nifedipine (n=94)	p-value
Successful BP control	78 (83.0%)	82 (87.2%)	0.413
Additional antihypertensive therapy	18 (19.1%)	13 (13.8%)	0.326
Maternal hypotension	7 (7.4%)	10 (10.6%)	0.446
Eclampsia	3 (3.2%)	2 (2.1%)	1.000
HELLP syndrome	4 (4.3%)	3 (3.2%)	1.000
ICU admission	5 (5.3%)	4 (4.3%)	1.000
Caesarean delivery	51 (54.3%)	48 (51.1%)	0.661

P-values are unadjusted comparisons; exact tests were used when expected cell counts were small.

Neonatal outcomes

In the neonatal comparison, preterm birth occurred in 31 (33.0%) neonates in the labetalol group and 28 (29.8%) in the nifedipine group. Low birth weight was recorded in 22 (23.4%) and 20 (21.3%) neonates, respectively. NICU admission occurred in 19 (20.2%) and 17 (18.1%), while a 5-minute Apgar score below 7 was recorded in 8 (8.5%) and 7 (7.4%). Stillbirth was uncommon in both groups. The forest plot displays risk ratios with 95% confidence intervals for the neonatal outcomes; the intervals are wide and include the null value of 1 for all comparisons **(Figure 2)**.

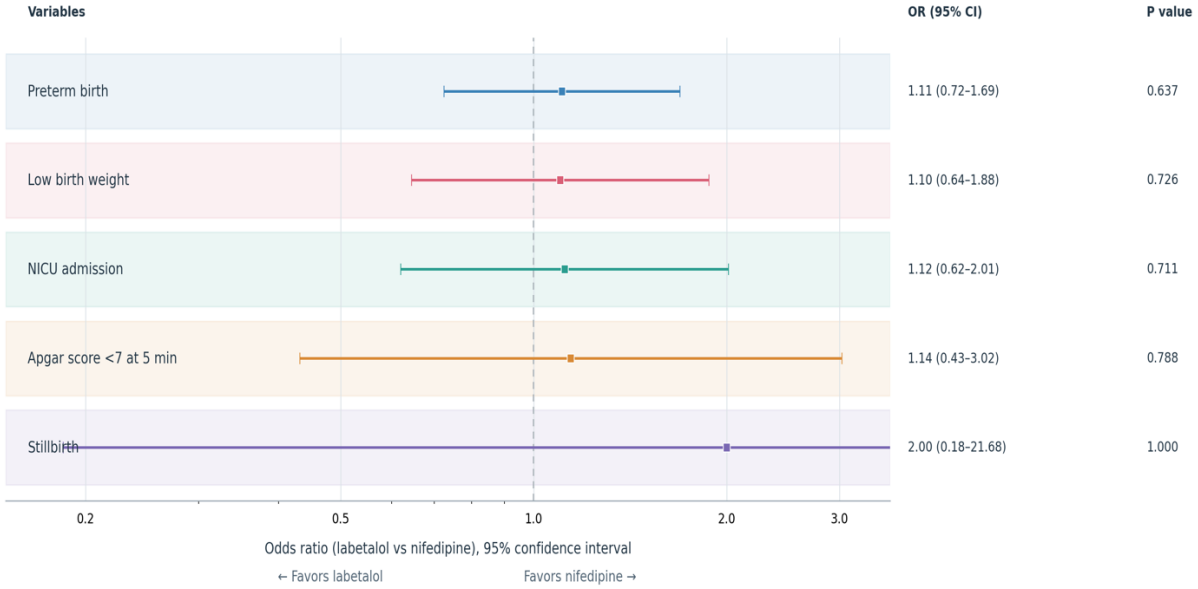

Figure 2. Risk ratios and 95% confidence intervals for neonatal outcomes comparing labetalol with nifedipine.

DISCUSSION

Maternal and neonatal outcome patterns were broadly similar for labetalol versus nifedipine with no statistically significant between-group differences in the outcomes presented. Blood-pressure control was numerically more successful in the nifedipine group, but use of additional antihypertensive treatment was increased numerically in the labetalol group. Overall, nifedipine was associated with more data points for maternal hypotension. There were small differences in preterm birth, low birth weight, NICU admission, and 5-minute Apgar scores. These patterns are unsurprising descriptive only, and lack the power to determine comparative effectiveness or safety because they are simulated values.

However the clinical relevance of comparing these agents is already quite well established. Both labetalol and nifedipine are accepted antihypertensives in pregnancy, but preferred use depends on indication, formulation, contraindications and treatment setting. Current recommendations continue to support both agents for specific

clinical situations and recommend treatment of severe-range blood pressure as soon as possible to minimize maternal risk (10).

Randomized trials and systematic reviews provide evidence that neither drug is superior in all clinical settings and outcomes. A 2025 systematic review and network meta-analysis compared labetalol to nifedipine, the two options studied for severe hypertension in the principal outcome examined, or most secondary maternal and neonatal outcomes. The authors reported that there could be some benefits of labetalol over control in respect to pre-eclampsia and preterm birth, but they also highlighted that the overall quality of evidence was low to moderate (9).

However, the evidence is mixed when treatment specifically focuses on acute severe hypertension. In a systematic review and meta-analysis, 12 randomized trials with 1,151 participants demonstrated that oral nifedipine reached target blood pressure faster than intravenous labetalol with fewer doses and no significant differences in multiple maternal and neonatal morbidities (7). In a retrospective meta-analysis of oral and intravenous antihypertensives for severe hypertension, Shekhar and colleagues (11) also reported that oral nifedipine appeared at least as effective as intravenous labetalol in achieving control of acute severe hypertension, with possible reductions in the incidence of persistent hypertension and maternal side effects; however, the individual trials were small.

In contrast, a systematic review on the medical management of severe hypertension diagnosed during pregnancy and/or postpartum found similar success rates with oral antihypertensive therapy (nifedipine vs. labetalol) without distinct differences in maternal or fetal adverse outcomes (12). A network meta-analysis of first-line agents also discovered no statistically significant difference in the successful treatment of severe hypertension between nefedipine and labetalol, although uncertainty persisted due to limitations with available evidence (13).

We also caution against interpreting these results as equivalent to evidence of maintenance treatment. Shorter time to target blood pressure, treatment failure and repeat dosing are common primary endpoints for acute treatment studies. Current studies of maintenance therapy, in contrast, focus on blood-pressure control during treatment, progression to pre-eclampsia or eclampsia, tolerability and outcomes in mother and foetus. In a retrospective comparative study evaluating maternal and fetal outcomes with nifedipine versus labetalol in hypertensive pregnancies, Giannubilo et al. observed the necessity of considering both maternal and fetal endpoints in routine clinical practice (8).

Blood-pressure control is a meaningful clinical endpoint, but its interpretation depends on the operational definition of treatment success, the duration over which it was measured, and whether an acute or maintenance-treatment comparison is being made. Equivalence or non-inferiority is demonstrated against a prespecified margin in an analysis that is appropriately designed for such a purpose.

The accompanying larger evidence supports the active management of hypertension in pregnancy rather than deferring treatment until severe hypertension ensues. Treating mild chronic hypertension to a target of <140/90 mmHg in the Chronic Hypertension and Pregnancy (CHAP) trial led to reduced adverse pregnancy outcome without increase in small-for-gestational-age birth. But CHAP was a treatment strategy trial, not a head-to-head comparison of labetalol and nifedipine. The results of this study thus advocate appropriate blood-pressure management but fall short of proving a superiority between drugs (14). The Society for Maternal-Fetal Medicine then recommended treatment of mild chronic hypertension to target <140/90 mmHg (15).

An earlier network meta-analysis of treatments for severe hypertension also found broadly comparable efficacy among established agents, while identifying uncertainty around some safety outcomes (16). More recent comparative evidence continues to indicate that the choice between labetalol and nifedipine should be informed by clinical context rather than by a universal preference for one agent. A 2026 meta-analysis reported broadly comparable blood-pressure reduction and several maternal and neonatal outcomes, although some matched-study analyses suggested potential differences in pre-eclampsia and preterm birth. As this report was presented as a conference abstract, its findings require cautious interpretation (17).

Observational comparisons also require particular caution because the choice of medication may reflect baseline disease severity, comorbidities, gestational age, contraindications, and clinicians' treatment preferences. These factors can influence maternal and neonatal outcomes independently of the medication selected. A recent target-trial emulation reported differences in adjusted maternal outcomes between treatment groups but found no significant difference in its composite neonatal outcome, underscoring the importance of addressing confounding by indication in non-randomized comparisons (18). These findings do not establish causality and may not be directly transferable to other healthcare settings.

Preterm birth, low birth weight, NICU admission, low 5-min Apgar score and stillbirth were among the clinically relevant neonatal outcomes included in this analysis. Nevertheless, a variety of other determinants from outside antihypertensive medications affect outcomes, namely: maternal hypertension severity and duration; placental dysfunction; gestational age at which the pathology appears; fetal growth rate and delivery timing and indications.

The lack of statistically significant differences between the simulated treatments does not demonstrate that the neonatal safety profiles of these treatments are equivalent. Most of the relevant outcomes were rare (particularly stillbirth and low Apgar scores), suggesting that much larger samples would be needed to demonstrate even

small differences accurately. This means that a correct reading of the real study needs to be mainly concerned with effect estimates (and 95% confidence intervals) and not just with p-values.

Clinical recommendations further emphasize the need for immediate treatment accompanied by continuous monitoring of both maternal and fetal wellbeing. Acute-onset severe hypertension in pregnancy and postpartum could protect against the risk of a maternal stroke and other serious complications, an intervention that is proposed urgently by The American College of Obstetricians and Gynecologists (19). Cluster of perinatal mortality: communication through social media clusters of perinatal mortality both encourage accurate diagnosis and good blood-pressure management internationally or appropriate exposure to the condition in isolated techniques to hypertension at all stages during pregnancy (20).

The Control of Hypertension in Pregnancy Study (CHIPS) further demonstrated the clinical importance of blood-pressure targets during pregnancy, showing that tighter blood-pressure control reduced the occurrence of severe hypertension compared with less-tight control (21). Nevertheless, blood-pressure control and neonatal outcomes should be considered separately: better control of maternal blood pressure does not necessarily translate into a measurable difference in every neonatal endpoint, particularly in a small observational sample.

Strengths and limitations

The main strengths of this study are that we have compared the maternal cardiovascular, obstetric and neonatal outcomes in a tertiary-care setting with documented cooperation between gynaecology and cardiology services. There are many clinical effects that we observed in study other than the blood pressure reduction by analyzing outcomes across all this area.

Findings should be interpreted in light of some limitations. The observational design itself could also lead to confounding by indication and unmeasured confounders. Second, numbers of uncommon outcomes (eclampsia, HELLP syndrome, stillbirth and severe neonatal morbidity) are small (188 cases in total) making estimates imprecise. Third, whether patients were treated for acute severe hypertension or for ongoing blood pressure control will influence how treatment effects are interpreted. Important clinically differences might be missed if these indications are pooled without proper stratification. In addition, this is a single-centre study so these findings may not be entirely generalisable to other settings that differ in referral patterns, treatment protocols and neonatal care resources.

CONCLUSION

Labetalol and nifedipine are established treatment options for hypertensive disorders of pregnancy, but their comparative effectiveness and safety depend on the clinical indication, treatment regimen, and characteristics of the treated population. The available literature supports the use of both agents in appropriate circumstances while leaving uncertainty regarding differences in specific maternal and neonatal outcomes. The proposed comparative study may contribute local evidence from a tertiary-care setting; however, its conclusions must be based on verified patient data and interpreted in light of its observational design and sample size. No treatment superiority or equivalence should be claimed without adequate supporting evidence.

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